

FREQUENTLY ASKED QUESTIONS (FAQ)

Clinical laboratory licensing and registration
Of physician office laboratories or clinics

Laboratory Field Services
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<http://www.dhs.ca.gov/ps/lsl/lfsb/default.htm>

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QUESTION	ANSWER
What is a clinical laboratory?	A clinical laboratory is defined in state and federal law as any place where testing is done on human specimens for diagnostic purposes.
Would a physician office laboratory (POL) be considered a clinical laboratory?	Yes, a POL is considered a clinical laboratory if any patient testing is done (e.g., urine dipstick tests, fingerstick blood tests or Pap smear review and reporting, for example).
Why do clinical laboratories need to be licensed or registered?	State law requires it. Licensing and registration of clinical laboratories helps assure that quality standards are maintained in clinical laboratories. Licensure or registration is part of the process that may include inspections, complaint review and proficiency testing oversight.
What is the difference between laboratory licensure and registration?	Laboratories doing non-waived testing are required to be inspected and licensed. Laboratories doing waived or provider-performed microscopy only need to be registered, although some waived laboratories may also be inspected.
Are there some laboratories that are exempt from licensure or registration?	A few types of laboratories are excluded from licensing and registration requirements. These include veteran's hospitals, public health laboratories, forensic laboratories, and research or teaching laboratories.
What about POLs? Are they excluded from licensure or registration requirements?	No, State law requires that POLs be licensed or registered.
What type of facility is considered a POL in California law?	A POL is a group of 5 or fewer physicians who do testing only on their own patients, do not perform any testing for other physicians, and do not perform HIV testing or review Pap smears.
Is there any benefit in California to be classified as a POL?	A POL may employ any competent person to do testing in their office laboratory. Testing persons do not need to be state licensed, but must meet federal requirements and be supervised by a physician.

Is it true that if my office qualifies as a POL and needs to get a state license that I don't have to hire licensed clinical laboratory scientists.	That's right. A POL that meets the definition above and is licensed does not need to employ licensed testing personnel. A POL would need to meet all laboratory license requirements.
Our POL has been paying CLIA fees for many years. Why do we have to also pay fees to the state?	Clinical laboratories in California are subject to two kinds of regulations—state and federal. Federal CLIA fees go to the Centers for Medicare & Medicaid Services which is responsible for assuring all laboratories in the US comply with federal standards. Licensing and registration under state law is in place to ensure that all laboratories in California comply with state standards. There are many ways that state and federal standards differ.
I hear there are similarities between state and CLIA standards. Why can't one system be used in California? What do I gain from double systems?	There are important differences between state and federal law. Clinical laboratories in California have had to comply with standards in state law since 1926. California clinical laboratory law provides important additional protections and quality assurance for clinical laboratory testing done in this state.
Is there any way that California can eliminate dual oversight and dual fees for clinical laboratories?	Yes, if California can prove to the federal government that all laboratories in California comply with federal standards, and that the state can assure ongoing compliance, then the state can take on administration of both the state and federal programs as a single program. This is called "CLIA exemption" and was attempted from 1996 to 2001.
I have never paid fees to the state before. What is different now that we have to start paying laboratory fees?	The Department of Health Services has decided to again pursue CLIA exemption to eliminate federal oversight in California. In order to do that, it must make sure that all laboratories comply with state law, and that state law is at least as strict as federal law.
How long will this whole process take?	It will take several years for all laboratories in California to be licensed or registered, for the state's federal CLIA exemption application to be prepared, and for a final decision to be rendered by the federal government.
When do I have to apply for licensure or registration?	If your laboratory is required to be licensed or registered, you will be notified by the Department of Health Services.
Are there some laboratories which do not need to be licensed or registered right away?	Yes, if on December 31, 1995 you were not required to obtain a state license pursuant to Business and Professions Code Section 1241, your CLIA certificate will continue to serve as your state registration or license until regulations are changed (anticipated in 2006) provided that the CLIA certificate is for the type and complexity of laboratory tests performed by you at this time and it has remained in effect, unsuspended and unrevoked the entire period.
Why was licensure or registration delayed for these laboratories?	Emergency regulations were passed during an attempt to gain CLIA exemption in 1996. This allowed a CLIA certificate to serve as a state license or registration temporarily until CLIA exemption was achieved. In order to apply for CLIA exemption now, all laboratories in California must be licensed or registered to ensure they comply with state law.

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